SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

Contact Person
Craig Coombs
Vice President, Regulatory/Clinical Affairs & Quality Assurance
415.531.1932
650.321.3908 fax
cjcoombs@aol.com

Device Name
Trade Name: Palmo Thermoregulation Interface Accessory
Common Name: System, Thermal Regulating
Classification Name: Thermal Regulation System Accessory (21 CFR 870.5900)

Predicate Devices

Cincinnati Subzero Blanketrol II Hyper-Hyopthermia System	Preamendment
Aquarius Thermo-STAT System	K970376

Device Description
The Palmo consists of three main parts: 1) a vacuum chamber that contains the 2) thermal exchange surface and an 3) arm seal.

The patient inserts his/her hand through the arm seal and into the vacuum chamber. The palm is placed on the thermal exchange surface. A light vacuum is created by connecting the Palmo to the hospital's regulated vacuum source. The physician can monitor the adequacy of the vacuum and seal from the dial on the mechanical vacuum gauge attached to the top of the Palmo unit. A light vacuum is applied to increase the amount of blood available in the appendage.

The Cincinnati Subzero Blanketrol II (or equivalent) creates the temperature-controlled water that flows through the water channels of the Palmo and heats/cools the thermal exchange plate. The thermal exchange surface is warmed if the patient needs to have the body core temperature increased, and cooled if the body core temperature needs to be decreased.

This combination of light vacuum and a thermal exchange surface provides a rapid and noninvasive mechanism for changing the temperature of the blood flowing through the appendage. This, in turn, changes the temperature of the body core.

The arm seal of the Palmo is available in three different sizes (small, medium & large) to accommodate the range of possible hand and wrist sizes of patients. A variation of the device can also be applied to the foot.

Indications for Use

The Palmo Thermoregulation Interface Accessory for the Cincinnati Subzero Blanketrol II is designed to noninvasively lower or raise a patient's temperature and/or maintain a desired patient temperature. This is accomplished with local application of negative pressure and heating/cooling to distal appendage.

Testing in Support of Substantial Equivalence Determination

The results of bench testing support the substantial equivalence claims of the Palmo Thermoregulatory Interface Accessory in the above claims. Earlier human studies have demonstrated that the simultaneous application of light vacuum and thermal exchange can effectively and noninvasively change the body core temperature of a patient.

Substantial Equivalence Conclusion

Substantial equivalence is based on the fact that the Palmo Thermoregulatory Interface Accessory has the same intended use as the CSZ Hyper-Hypothermia system. Both use the same CSZ Blanketrol II as a source of temperature controlled water.

The Palmo is also substantially equivalent in intended use and technology as the Aquarius Thermo-STAT System. The technology uses a local application of negative pressure and a thermal exchange surface to a distal appendage. As demonstrated in the bench testing, there are no significant differences in technology between the two systems. There are no new questions of safety or efficacy raised between the two systems

Therefore, it can be concluded that the Palmo Thermoregulatory Interface Accessory is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2002

AVAcore Technologies, Inc.
c/o Mr. Craig J. Coombs
Vice President
Regulatory/Clinical Affairs & Quality Assurance
251 High Street, Suite B
Palo Alto, CA 94301

Re: K014210
Trade Name: Palmo Thermoregulation Interface Accessory
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System Accessory
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: May 24, 2002
Received: May 28, 2002

Dear Mr. Coombs:

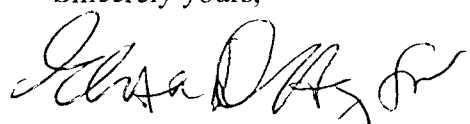
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014210

Device Name: Palmo Thermoregulation Interface Accessory

Indications for Use

The Palmo Thermoregulation Interface Accessory is designed to noninvasively lower or raise a patient's temperature and/or maintain a desired patient temperature. This is accomplished with local application of negative pressure and heating/cooling to a distal appendage.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

8/15/02